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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,118	06/28/2000	R. C. Quijano	VENPROO.007C1	6405

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Dr

<b>Office Action Summary</b>	Application N . 09/605,118	Applicant(s) QUIJANO ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 December 2001.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30-50 is/are pending in the application.
- 4a) Of the above claim(s) 39-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 30-41, drawn to a valvular prosthesis, classified in class 623, subclass 1.24.
- II. Claims 42-46, drawn to a method of making a vascular prosthesis, classified in class 600, subclass 36.
- III. Claims 47-50, drawn to a method of using a vascular prosthesis, classified in class 623, subclass 1.24.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process that does not include chemically fixing the vascular prosthetic.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product as claimed can be practiced with another materially different product that does not include a biological valve; but includes a synthetic valve.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and searches, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: Fig. 4.

Species II: Fig. 5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 30 and 47 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Victoria Sandberg on 2/5/02 a provisional election was made with traverse to prosecute the invention of Group I, claims 30-41. Affirmation of this election must be made by applicant in replying to this Office action. Claims 39-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30-33, 38 rejected under 35 U.S.C. 102(b) as being anticipated by Herweck et al. (5197976). Herweck et al. disclose vascular grafts are formed from, veins, which inherently include biological valves, col. 1, lines 48-52. Herweck also discloses the repair of arterial and venous vessels, col. 1, lines 65-67. Additionally, the device can be formed such that the single inflow end is formed with a greater diameter by joining two grafts together. Herweck discloses that two biological grafts can be sutured together, col. 3, lines 4, 5.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 30-34, 37, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Quijano et al. (5500014) in view of Herweck et al. (5197976). Quijano et al. disclose valvular prostheses can be formed from a biological graft with a biological valve for defective blood vessels, col. 5, lines 10-15. Quijano also discloses valved conduits are needed to repair larger vessels, col. 14, lines 51-59 and can be modified to meet the requirements of the vessel to be repaired. With respect to claim 34, the valves are fully

capable of opening at pressures as low as 1mm Hg and remain sealably closed to withstand backflow pressure greater than 200 mm Hg. However, Quijano does not disclose joining two segments for a bifurcated section of a damaged vessel. Herweck et al. teach to join two conduits together at adjacent inflow ends (Figs. 4 and 6A) forming a vascular prosthetic where the joined end has a cross-sectional area larger than any of the inflow ends of the conduits and the outflow ends can be used for a bifurcation. Herweck also teaches that the two ends can be joined to form one lumen, col. 2, lines 40-42. It would have been obvious to one of ordinary skill in the art to use two conduits as taught by Herweck for the graft of Quijano in order to provide a vascular prosthesis for use in blood vessels comprising branched vessels.

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herweck et al. '976. Herweck is explained supra. However, Herweck does not disclose the cross-sectional area of the inflow end of the graft being greater than 22 or 28mm. It would have been an obvious expedient to have an inflow end with a cross-sectional area greater than 22 or 28 mm, since applicant has not disclosed that this diameter provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the dimension taught by Herweck or claim 35 or 36 dimensions because both ends perform the same function of providing an increased diameter at the inflow end, considering the typical size of an artery.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 9-13, 24, 25 of U.S. Patent No. 6110201. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims recite having two valvular conduits with biological valves therein joined together at one end forming a larger end with a cross-sectional area greater than a cross-sectional area of either of the two joined segments.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Response to Arguments***

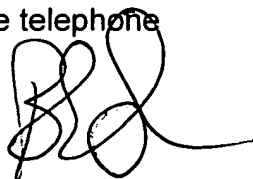
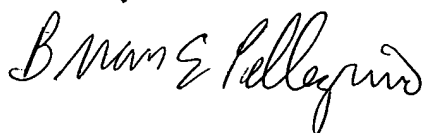
Applicant's arguments filed 11/2/01 have been fully considered but they are not persuasive. Regarding the combination of Quijano and Herweck would have been obvious because a motivation can be found when requiring a graft to be placed in a bifurcated area. Thus one of ordinary skill in the art would look for teachings of joined segments and can be found in Herweck, col. 3, lines 4, 5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino February 8, 2002

TC 3700, AU 3738



BRUCE SNOW  
PRIMARY EXAMINER